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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,304	04/14/2004	Lucio Giambattista	P-5023D1	5970
7590 02/01/2006			EXAMINER	
Becton, Dickinson and Company 1 Becton Drive Franklin Lakes, NJ 07417			GILBERT, ANDREW M	
			ART UNIT	PAPER NUMBER
			3767	
DATE MAILED: 02/01/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/824,304

Applicant(s)

GIAMBATTISTA ET AL.

Examiner

Andrew M. Gilbert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 24-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the indicating areas and visual indications must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Specification***

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: a description of the claimed indicating areas and visual indications must be disclosed.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 25-35, 37-44, 46-49, 51-52, 54-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The applicant fails to teach or disclose any reference to a visual indicator, indicating area, or additional claimed details of a visual indicator and indicating area in the specification and drawings.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 24, 31, 36, 45, 50, and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Berthier (5429612). In reference to claim 24, Berthier discloses a safety injection needle assembly (1) having an injection needle (6) with an injection end and a cartridge end (Fig 1), the needle being mounted in a hub (2; Fig 1, 2; col 3, lns 23-27), a slideable safety shield (10) being biased to longitudinally slide toward and cover the injection end of the needle in the normal unused state (Fig 1), a lock (12, 16) that is activated by sliding the shield from its biased position to a position exposing the injection end of the needle during an injection (col 3, ln 33-col 4, ln 8) and a visual indicator (10) that indicates that the safety shield is locked in the normally biased position (Fig 1).

7. In reference to claim 31, it is noted that the applicant has invoked 35 U.S.C. 112(6<sup>th</sup>) paragraph in claims 31, pg 5, ln 6 by fulfilling the 3-pronged test by reciting "means for" language, reciting function, and by not including or reciting sufficient structure of the means referred to in the specification. Berthier discloses the invention substantially as claimed and additionally discloses a locking means for irreversibly locking the safety shield in the second position covering the injection end of the needle being a lock (12, 16) that is activated by sliding the shield from its biased position to a position exposing the injection end of the needle during an injection (col 3, ln 33-col 4, ln 8).

8. In reference to claim 36, Berthier discloses the invention substantially as claimed except for additionally disclosing that the needle hub has a proximal end having a fastening mechanism (2) for mounting the needle hub onto a syringe having a cartridge

(4), an injection end of the needle that is capable of subcutaneous injection (col 2, lns 48-56), and a cartridge end that extends into the interior of the cartridge (Fig 1).

9. In reference to claims 45 and 50, Berthier discloses the invention substantially as claimed and additionally discloses a vial end (6; 2; 5; Fig 1; col 3, lns 10-22) and a lock and safety shield that are constructed and arranged to provide a visual indication that the safety shield is locked in the normally biased position (12; 16; 10; Fig 1).

10. In reference to claim 53, Berthier discloses the invention substantially as claimed and additionally discloses a needle hub having a closed end (2) and an open end (opposite end of 2 seen in Fig 1), the open end being provided with a thread (seen on 3; col 3, lns 10-15) to mount the needle hub to an injector having a vial (4) covered by the needle hub (2).

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 25-30, 32-35, 37-44, 46-49, 51-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berthier in view of Lewandowski (5674203).

13. In reference to claims 25-30, 32-35, 37-40, 41-44, 46-49, 51-52, and 54-57, Berthier discloses the invention substantially as claimed except for the lock or hub having an indicating area and at least one additional indicating area, the safety shield having a transparent area or an opening through which the indicating areas are visible,

the indicating areas and additionally indicating areas providing difference visual indications, and the visual indication showing a colored surface or textured surface after the shield is irreversibly locked. Lewandowski teaches that it is known to have the lock or hub having an indicating area and at least one additional indicating area (Figs 1-13; col 4, ln 46-col 7, ln 13), the safety shield having a transparent area (40; col 5, lns 10-15) or an opening (31) through which the indicating areas are visible (Figs 1-13), the indicating areas and additionally indicating areas providing difference visual indications (Figs 1-13), and the visual indication showing a colored surface (Figs 1-13; col 4, ln 46-col 7, ln 13) or textured surface (Figs 1-13; col 4, ln 46-col 7, ln 13), as any printing or coating will result in a textured surface, after the shield is irreversibly locked for the purpose of providing a visual indication that the needle guard is in the extended and locked position without the need for further testing on the part of the user (col 4, lns 58-61). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the needle shield as taught by Berthier with the needle shield as taught by Lewandowski for the purpose of providing a visual indication that the needle guard is in the extended and locked position without the need for further testing on the part of the user (col 4, lns 58-61).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Andrew Gilbert

